

REMARKS

Applicant appreciates the Examiner's thorough examination of the subject application and request reconsideration of the subject application based on the foregoing amendments and the following remarks.

Applicant also acknowledges with thanks the personal interview with Examiner Scott and her supervisor concerning the above-identified Office Action, the cited art and the claims, including amending some of the claims to distinguish from the cited art.

Claims 1, 9, 15, 26-31, 37-41, 46-49, 57-60, 65-68 and 73-80 are pending in the subject application. Claims 2-8, 10-14, 16-25, 32-36, 42-45, 50-56, 61-64 and 69-72 were previously canceled. It should be noted that claim 9 is not listed in the Disposition of Claims section on the Office Action Summary page of the above-referenced Office Action, however, claim 9 does appear in the discussion regarding the grounds for rejection. Thus, Applicant respectfully requests that the records of the USPTO be updated if required.

Claims 1, 9, 15, 26-31, 37-41, 46-49, 57-60, 65-68 and 73-80 stand rejected under 35 U.S.C. §102 and/or 35 U.S.C. §103. Claims 41 and 48 were objected to because of identified informalities.

Claims 1, 15 and 26 were amended in the foregoing amendment so as to provide that the deflection mechanism extends within the elongated member (claims 1 & 15) or within the catheter device (claim 26). Claims 1, 15 and 26 as well as claims 27-31, 37-41, 46-49, 57-60, 65-68 and 73 were amended so that they are in better form.

Claims 41 and 48 were amended to address the identified informalities.

As the amendments to the claims are supported by the originally filed disclosure (including the originally filed claims of the PCT application), entry of such amendments into the subject application is respectfully requested.

35 U.S.C. §102 & 35 U.S.C. §103 REJECTIONS

The Examiner rejected claims 1, 9, 15, 26-29, 37-39, 46-49, 57-59, 65-67 and 73-80 under 35 U.S.C. §102(b) as being anticipated by Lesh [USP 5,971,987]. Claims 30-31, 40-41, 60-68 stand rejected under 35 U.S.C. §103 as being unpatentable over Lesh in view of Hall [USP 6,652,517]. Applicant respectfully traverses as discussed below.

Because claims were amended in the instant amendment, the following discussion refers to the language of the amended claims. However, only those amended features specifically relied upon to distinguish the claimed invention from the cited prior art shall be considered as being made to overcome the cited reference. The following addresses the within §102 & §103 rejections as to the below identified groupings of claims.

CLAIMS 1 & 9

In claim 1, Applicant claims a catheter device that includes an elongated body member having a distal portion and a deflection mechanism that is operably coupled to the distal portion so as to cause the distal portion to deflect with respect to a longitudinal axis of the elongated body member. Such a deflection mechanism extends within the elongated body and is operably coupled to the distal portion. As indicated herein, without agreeing with the rejection and in the interests of advancing prosecution, claim 1 was amended to further provide that the elongated has an end and also that --the distal portion is that portion of the elongated body member extending from the guiding mechanism exit portion to an the end of the elongated body member--.

Such a catheter device further includes a guide member and a guiding mechanism. Such a guiding mechanism is coupled to the elongated body member and configured so as to guide the guide member. As noted above, the guiding mechanism includes an exit portion from which the guide member exits when the guide member is being deployed from the guiding mechanism. The exit portion is disposed with respect to the distal portion so the distal portion deflects from and with respect to the guide member, when the guide member is in a deployed condition.

In contrast to the present invention, the catheter device in Lesh includes two guide wires so that a portion of the catheter device including an ablation mechanism, can be pinned or located between two points (fixed points) and so that said portion can abut and be in contact with tissue. In this way, when the ablation mechanism is activated, a linear or line of ablated tissue is formed using such a catheter device.

In contrast, the distal portion of the catheter device of the present invention which includes the end of the distal portion is deflectable with respect to the long axis of the elongated body member as well as the from and with respect to the guide (when it is deployed). As a result of this deflectability, the deflectable portion can be deflected and manipulated so a non-linear band of ablated tissue (e.g., a ring of ablated tissue) is formed about the guide wire.

As described in Lesh, the guide wires 3,4 are deployed and secured to tissue in the left and right pulmonary veins. After such placement of the guide wires, the catheter device (portions thereof) are advanced over the guide wires until they are disposed in the desired arrangement. For example, the distal guide tracking member 30 or distal end portion is advanced over one guidewire 3, until the first distal guidewire port 32 confronts stop 13. The other port identified by reference numeral 34 is an entrance port where the guide wire enters into the catheter until it exits at the first distal guidewire port.

The advancement of the catheter device is continued until the catheter becomes pinned between the two points defined by the two guide wires 3,4 (as described above) and until the intermediate portion of the catheter is put into contact with the tissues. In other words, such advancement in combination with the passive bending properties of the catheter allows the intermediate portion of the catheter to bend until it comes in contact with the tissues.

Also, and as shown in the annotated Fig. 5 included with the above-referenced Office Action, the portion of the catheter device having the end thereof is disposed about one of the guide wires 3. As also can be concluded from Fig. 5 and the discussion in the Lesh, it is not possible for this portion of the catheter device to be deflected with respect to the guide wire because the guide wire is within that portion of the catheter device having the end. Therefore, Lesh cannot describe,

teach or suggest a catheter device where the device includes an elongated body member having a distal portion and an end, a guiding mechanism that includes an exit portion, where the exit portion is disposed with respect to the distal portion so the distal portion deflects from and with respect to the guide member, when the guide member is in deployed condition and wherein the distal portion is that portion of the elongated body member extending from the guiding mechanism exit portion to the end of the elongated body member. Also Lesh does not describe nor teach a deflection mechanism that extends within the elongated body and that is operably coupled to the distal portion so as to cause the distal portion (*i.e.*, the portion including the end) to deflect with respect to a longitudinal axis of the elongated body member.

As previously indicated by Applicant, the first distal guidewire port 32 is located in the distal end 32 of the catheter device or the distal end portion thereof. In such a configuration, the guide wire exits from the distal end 32 of the catheter device. Such a configuration precludes the distal end portion of the catheter in Lesh from being deflected from and with respect to the guide wire when the guide wire is deployed because the guide wire is inside the distal end portion.

In sum, Lesh does not describe the catheter device of claim 1 for at least the foregoing reasons.

In this regards, Applicant also would note that the subject specification provides that a deflection mechanism “can deflect the distal portion of the elongated body member with respect to the guide member and thus place the operable end of the distal portion in contact with the tissues to be ablated” and the subject application also provides that as known to those skilled in that art, “a catheter having a deflection mechanism is configured so that the distal portion of the elongated body member will deflect or move (*e.g.*, curve) with respect to a longitudinal axis of the elongated body member and about a specific point from the end of the distal portion. For example, groups of wires are attached or secured to the distal portion and are arranged so that when they are operated in specific ways, the distal portion of the catheter is moved with respect to the long axis of the body member. As is also known to those skilled in the art, such deflection mechanisms can be arranged and operated so that the end of the distal portion can be deflected or

curved back upon itself so the end is pointing in a direction that is opposite to the general direction of other portions of the elongated body member (*e.g.*, forming a hook like arrangement).”

In addition, the subject application provides that, “a catheter device such as that of the present invention can be configured and arranged with any one of a number of devices or mechanisms, herein referred to as a deflection mechanism, that can be actuated or operated so as to cause a distal portion 112 of the elongated body member 110 to deflect or be moved with respect to the longitudinal axis 102 of the elongated body member. For example, groups of wires are attached or secured to the distal portion and are arranged so that when they are operated in specific ways, the distal portion of the catheter is moved with respect to the long axis of the body member. In a particularly illustrative example and as illustrated in Fig. 2B, the deflection mechanism causes the distal portion 112 to be deflected with respect to a deflection point 104.

Thus it is further respectfully submitted that there is no mechanism, device or structure described in Lesh that corresponds in any fashion to a “deflection mechanism” as that term is used in the claims and described in the subject application.

Applicant thus submits that Lesh does not teach, suggest such features of claim 1 or modifying the catheter device described in Lesh so as to yield the catheter device as set forth in claim 1. Applicant also would note that any modification to the device in Lesh so as to yield the claimed device would necessarily involve the impermissible destruction of the Lesh device.

Thus, claim 1 is considered to be patentable over Lesh for the foregoing reasons.

As to claim 9, this claim depends (directly or ultimately) from claim 1. Thus, claim 9 is considered to be allowable at least because of its dependency from an allowable base claim. This shall not be considered an admission that this claim is not otherwise patentable over Lesh. In this regard, Applicant makes the following further observations.

Claim 9 includes the further limitation that the guiding mechanism includes an artifact on the external surface of the elongated body member and extending axially along the elongated body member, where the artifact and the guide member are configured and arranged so the guide

member is moveably retained by the artifact and so as to allow for deployment of the guide member. There is no guiding structure shown in Lesh in which the guiding mechanism is on an external surface of the elongated body member and which guiding mechanism also extends axially along the elongated body member.

It is respectfully submitted that claims 1 and 9 are patentable over the cited reference for the foregoing reasons.

CLAIM 15

Applicant respectfully submits that the above remarks distinguishing the catheter device of claim 1 from Lesh also at least applies to distinguish the catheter device of claim 15 from Lesh. This shall not be considered an admission that claim 15 is not otherwise patentable over Lesh. In this regard, Applicant makes the following further observation.

Claim 15, includes the limitation that “wherein the exit portion is configured and arranged so that the distal portion when in a deflected condition is rotatable about the guide member, when the guide member is in a deployed condition.”

As indicated in the above discussion regarding claim 1, the catheter device in Lesh includes two guide wires so that a portion of the catheter device including an ablation mechanism, can be pinned or located between two points (fixed points) and so that said portion can abut and be in contact with tissue. In this way, when the ablation mechanism is activated, a linear or line of ablated tissue is formed using such a catheter device.

These two guide wires naturally restrain the elongated body member or described catheter device from being rotated about either guide wire. For example, that portion of the catcher device including the end is disposed about the guide wire which prevents it from being deflected with respect to a long axis of the catcher device of the guide wire. Because of the pinning effect on the catheter device by the other guide wire 4, the catheter device cannot be rotated about the guide wire 3.

In Hall, a guiding catheter is provided to guide another device along the length of the guiding catheter until the circular end of the another device abuts the tissue. This does not teach rotating as claimed by Applicant. Moreover, any combination of references to modify the disclosure in Lesh so that the distal portion could rotate about the guide wire 3, would necessarily mean that the function of Lesh to form linear ablations of the tissue could not be performed.

It is respectfully submitted that claim 15 is patentable over the cited reference for the foregoing reasons.

CLAIMS 26-31

Applicant respectfully submits that the above remarks distinguishing the catheter device of claim 1 from Lesh also at least applies to distinguish the method for ablating tissue in particular atrial tissue of claim 26 from Lesh. This shall not be considered an admission that claim 26 is not otherwise patentable over Lesh.

As to claims 27-31, each of these claims depends (directly or ultimately) from claim 26. Thus, each of claims 27-31 is considered to be allowable at least because of their dependency from an allowable base claim. This shall not be considered an admission that these claims are not otherwise patentable over Lesh. In this regard, Applicant makes the following further observations.

Each of claims 28-31 includes the limitation(s) that the deflectable portion is being rotated about the guide wire. Applicant respectfully submits that the above further remarks distinguishing the catheter device of claim 15 from Lesh also at least applies to distinguish such rotating about the guide wire from Lesh.

It is respectfully submitted that claims 26-31 are patentable over the cited reference or combination of references for the foregoing reasons.

CLAIMS 37-41 & 73

Applicant respectfully submits that the above remarks distinguishing the catheter device of claim 1 and the method of claims 26-31 from Lesh also at least applies to distinguish the method for ablating tissue in particular atrial tissue of claim 37 from Lesh. This shall not be considered an admission that claim 37 is not otherwise patentable over Lesh. In this regard, Applicant makes the following further observations.

The method of claim 37 includes, *inter alia*, localizing an end of the deflectable distal portion with respect to an opening in a chamber, vessel or vein of a mammalian body and deploying the guide member from the guiding mechanism so at least a distal portion thereof is deployed through the opening in, and is disposed in, the chamber, vessel or vein of the mammalian body. As described above in the discussion regarding claim 1, in Lesh the guide wires 3,4 are deployed and then the catheter device is advanced over the guide wires into the desired arrangement. Thus, Lesh cannot describe or teach the above-described limitation of localizing the distal end and then deploying the guide member.

As to claims 38- 41 and 73, each of these claims depends (directly or ultimately) from claim 37. Thus, each of claims 38-41 and 73 is considered to be allowable at least because of their dependency from an allowable base claim. This shall not be considered an admission that these claims are not otherwise patentable over Lesh. In this regard, Applicant makes the following further observations.

Each of claims 38-41 further includes the limitation that the deflectable portion is being rotated about the guide wire. As indicated above, Applicant respectfully submits that the above further remarks distinguishing the catheter device of claim 15 from Lesh also at least applies to distinguish such rotating about the guide wire from Lesh.

It is respectfully submitted that claims 37-41 and 73 are patentable over the cited reference or combination of references for the foregoing reasons.

CLAIMS 46-49

Applicant respectfully submits that the above remarks distinguishing the catheter device of claim 1 and the method of claims 26-31 from Lesh also at least applies to distinguish the method for treating arrhythmias of claim 46 from Lesh. This shall not be considered an admission that claim 46 is not otherwise patentable over Lesh.

As to claims 47-49, each of these claims depends (directly or ultimately) from claim 46. Thus, each of claims 47-49 is considered to be allowable at least because of their dependency from an allowable base claim. This shall not be considered an admission that these claims are not otherwise patentable over Lesh. In this regard, Applicant makes the following further observations.

Each of claims 48 and 49 includes the limitation(s) that the deflectable portion is being rotated about the guide wire. As indicated above, Applicant respectfully submits that the above further remarks distinguishing the catheter device of claim 15 from Lesh also at least applies to distinguish such rotating about the guide wire from Lesh.

It is respectfully submitted that claims 46-49 are patentable over the cited reference or combination of references for the foregoing reasons.

CLAIMS 57-60

Applicant respectfully submits that the above remarks distinguishing the catheter device of claim 1, the method of claims 26-31 and the method of claim 37 from Lesh also at least applies to distinguish the method for treating arrhythmias of claim 57 from Lesh. This shall not be considered an admission that claim 57 is not otherwise patentable over Lesh. In this regard, Applicant makes the following further observations.

The method of claim 57 includes, *inter alia*, localizing an end of the deflectable distal portion within the left atrium of a mammalian body and with respect to an opening in a vein and deploying the guide member from the guiding mechanism so at least a distal portion thereof is deployed through the opening in, and is disposed in, the vein. As described above in the

discussion regarding claim 1 and claim 37, in Lesh the guide wires 3,4 are deployed and then the catheter device is advanced over the guide wires into the desired arrangement. Thus, Lesh cannot describe or teach the above-described limitation of localizing the distal end and then deploying the guide member.

As to claims 58-60, each of these claims depends (directly or ultimately) from claim 57. Thus, each of claims 58-60 is considered to be allowable at least because of their dependency from an allowable base claim. This shall not be considered an admission that these claims are not otherwise patentable over Lesh. In this regard, Applicant notes makes the following further observations.

Each of claims 58-60 further includes the limitation that the deflectable portion is being rotated about the guide wire. As indicated above, Applicant respectfully submits that the above further remarks distinguishing the catheter device of claim 15 from Lesh also at least applies to distinguish such rotating about the guide wire from Lesh.

It is respectfully submitted that claims 57-60 are patentable over the cited reference or cited combination of references for the foregoing reasons.

CLAIMS 65-68

Applicant respectfully submits that the above remarks distinguishing the catheter device of claim 1, the method of claims 26-31 and the method of claim 37 from Lesh also at least applies to distinguish the method for treating left atrial arrhythmia in a left atrium of a mammalian body of claim 65 from Lesh. This shall not be considered an admission that claim 65 is not otherwise patentable over Lesh. In this regard, Applicant makes the following further observations.

The method of claim 65 includes, *inter alia*, positioning an end of the deflectable distal portion with respect to an a pulmonary vein extending from the left atrium and deploying the guide member from the guiding mechanism so at least a distal portion thereof is deployed through the opening in, and is disposed in, the pulmonary vein. As described above in the

discussion regarding claim 1, in Lesh the guide wires 3,4 are deployed and then the catheter device is advanced over the guide wires into the desired arrangement. Thus, Lesh cannot describe or teach the above-described limitations of positioning and deploying of claim 65.

As to claims 66-68, each of these claims depends (directly or ultimately) from claim 65. Thus, each of claims 66-68 is considered to be allowable at least because of their dependency from an allowable base claim. This shall not be considered an admission that these claims are not otherwise patentable over Lesh. In this regard, Applicant notes makes the following further observations.

Each of claims 66-68 further includes the limitation that the deflectable portion is being rotated about the guide wire. As indicated above, Applicant respectfully submits that the above further remarks distinguishing the catheter device of claim 15 from Lesh also at least applies to distinguish such rotating about the guide wire from Lesh.

It is respectfully submitted that claims 65-68 are patentable over the cited reference or identified combination of references for the foregoing reasons.

CLAIMS 74-80

As to claims 74-80, each of these claims depends (directly or ultimately) from one of claims 1, 15, 26, 37, 46, 57 and 65, which claims are considered to be allowable. Thus, each of claims 74-80 is considered to be allowable at least because of their dependency from an allowable base claim. This shall not be considered an admission that these claims are not otherwise patentable over Lesh.

It is respectfully submitted that claims 65-68 are patentable over the cited reference for the foregoing reasons.

The following remarks also shall apply to each of the foregoing remarks.

As the Federal Circuit has indicated, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Or stated another way, "The identical invention must be shown in as complete detail as is contained in the ... claims. *Richardson v Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ 2d. 1913, 1920 (Fed. Cir. 1989). Although identify of terminology is not required, the elements must be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990). It is clear from the foregoing remarks that the above identified claims are not anticipated by Lesh.

As provided by the Federal circuit, a 35 U.S.C. §103 rejection based upon a modification of a reference that destroys the intent, purpose or function of the invention disclosed in a reference, is not proper and the prima facie case of obviousness cannot be properly made. In short there would be no technological motivation for engaging in the modification or change. To the contrary, there would be a disincentive. *In re Gordon*, 733 F. 2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

It is respectfully submitted that for the foregoing reasons, claims 1, 9, 15, 26-31, 37-41, 46-49, 57-60, 65-68 and 73-80 are patentable over the cited reference or cited combination of references and thus, satisfy the requirements of 35 U.S.C. §102(b) or 35 U.S.C. §103. Therefore, these claims are allowable.

CLAIM OBJECTIONS

As indicated above, claims 41 and 48 were objected to because of the identified formalities as described in the above -referenced Office Action.

As indicated above, each of these claims were amended to address the informalities. More particularly, the claims were amended as suggested by the Examiner.

Accordingly, it is respectfully submitted that claims 41 and 48 are acceptable.

It is respectfully submitted that the subject application is in a condition for allowance. Early and favorable action is requested.

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U.S.S.N.: 10/576,424
Response to Non-Final Office Action
Page 26 of 26

Applicant believes that additional fees are not required for consideration of the within Response. However, if for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, the Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1105, under Order No. 62270 (71699).

Respectfully submitted,
Edwards Angell Palmer & Dodge, LLP

/ William J. Daley, Jr. /

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